Citation:

Galeone C, Tavani A, Pelucchi C, Negri E, La Vecchia C. Allium vegetable intake and risk of acute myocardial infarction in Italy. *Eur J Nutr.* 2009 Mar;48(2):120-3. Epub 2009 Jan 13.

PubMed ID: 19142565

Study Design:

Case-Control Study

Class:

C - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine the relationship between the dietary intake of allium vegetables (onion and garlic) and acute myocardial infarction.

Inclusion Criteria:

Cases: admitted to an area hospital with a first episode non-fatal acute myocardial infarction (AMI).

Controls: admitted to the same hospitals for acute conditions not related to known AMI risk factors nor diet.

Exclusion Criteria:

Subjects with a history of major cardiovascular events.

Description of Study Protocol:

Recruitment

- All patients who were admitted to a hospital in the greater Milan, Italy area and who met the inclusion/exclusion criteria between 1995 and 2003 were approached.
- Data was used from 760 patients with a first episode of non-fatal acute myocardial infarction and 682 controls admitted to the same hospitals between 1995 and 2003

Design: Case-Control Study

Blinding used (if applicable): not applicable

Intervention (if applicable): not applicable

Statistical Analysis

- The ORs of acute myocardial infarction and 95% confidence intervals for different levels of onion intake and garlic use were derived using unconditional multiple logistic regression models.

Data Collection Summary:

Timing of Measurements

One interview during hospitalization, using structured questionnaire, clinical records and a food-frequency questionnaire (FFQ).

Dependent Variables

- Acute myocardial infarction

Independent Variables

- Onion and garlic intake, measured by FFQ for the two years prior to diagnosis
- For onion intake, weekly frequency of consumption was asked and usual portion size (small, intermediate, or large, where an intermediate portion corresponded to 80 g of onion)
- For garlic intake, frequency was coded as non-use/low use, intermediate use, or high use

Control Variables

- Age
- Sex
- Socio-demographic factors, such as education
- Anthropometrics, such as BMI
- Smoking
- Alcohol and coffee consumption
- Physical activity
- Cholesterol levels
- Medical history
- Dietary intake: energy, fish, vegetable

Description of Actual Data Sample:

Initial N: Cases: 760 (580 male, 180 female). Controls: 682 (439 males, 243 females)

Attrition (final N): as above, less than 5% of the cases and controls approached refused to participate.

Age: Cases: median age 61 years (range 19-79 y). Controls: median 59 years (16-79 y)

Ethnicity: not specified

Other relevant demographics:

Anthropometrics

Location: Milan, Italy

Summary of Results:

Key Findings:

- Compared with non-users, the odds ratios of acute myocardial infarctions for subsequent categories of onion intake were 0.90 (95% confidence interval: 0.69 - 1.21) for <1 portion of onion per week and 0.78 (95% confidence interval: 0.56 - 0.99) for >1 portion per week.
- For garlic, the odds ratios were 0.84 (95% confidence interval: 0.66 - 1.09) for intermediate and 0.94 (95% confidence interval: 0.68 - 1.32) for high use, compared with low or no use.

Other Findings

Variables	Cases:controls	OR (95% CI)[1]	OR (95% CI)[2]
Onion intake (portions per week)	384:308	1[3]	1[3]
non-users	192:173	0.87 (0.67-1.13)	0.90 (0.69-1.21)
>0-<1	184:201	0.69 (.054-0.90)	0.78 (0.56-0.99)
≥ 1		0.006	0.05
P for trend			
Garlic use			
None or low	290:252	1[3]	1[3]
Intermediate	330:315	0.90 (0.72-1.14)	0.84 (0.66-1.09)
High	139:114	1.10 (.081-1.49)	0.94 (.068-1.32)
P for trend		0.70	0.70

[1]Estimates from multiple logistic regression models, including age and sex

[2]Estimates from multiple logistic regression models, including age, sex, education, tobacco smoking, coffee, alcohol drinking, total energy intake, fish intake, vegetable intake, BMI, physical activity, cholesterol levels, history of hypertension, diabetes and family history of AMI in first-degree relatives

[3] reference category

Author Conclusion:

A diet rich in onions may have a favourable effect on the risk of acute myocardial infarction.

Reviewer Comments:

Cases and controls were not matched for age, sex, and other variables. Authors note that a

limitation of the study is that onion and garlic intake in Italy could be considered markers of a healthier lifestyle, which may include complex aspects of quantity and quality of diet, and in particular of a diet rich in cooked vegetables, which has been inversely associated with acute myocardial infarction.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	???
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes

3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	???
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	???
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	???
4.1.	Were follow-up methods described and the same for all groups?	???
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	???
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	Yes
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes

6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	N/A
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	N/A
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A

	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes